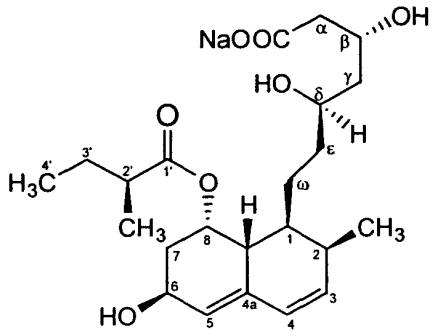
CLAIMS

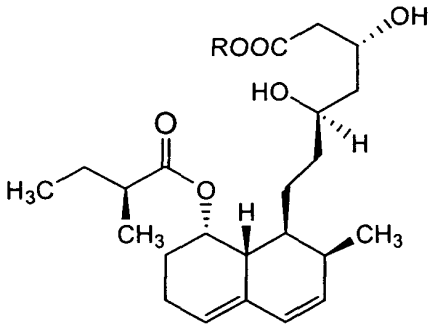
We claim:

1. A microbial process for the preparation of the compound of formula (I)



(I)

from a substrate compound of formula (II),



(II)

wherein R stands for an alkali metal or ammonium ion,

comprising the steps of

a) cultivating a strain of *Mortierella maculata* filamentous mold species able to 6β-hydroxylate a compound of formula (II) on a nutrient medium containing assimilable carbon and nitrogen sources and mineral salts,

b) feeding the substrate to be transformed into the developed culture of *Mortierella*

maculata,

c) fermenting the substrate until the end of bioconversion,

d) separating the compound of formula (I) from the culture broth, and

e) isolating the compound of formula (I).

2. The process of claim 1, wherein said medium is a nutrient broth.

3. The process of claim 2, wherein said step of separating the compound of formula (I) from the culture broth is performed by adsorption on an anionic ion exchange resin.

4. The process of claim 2, wherein said step of separating the compound of formula (I) from the culture broth is performed by extraction with a water immiscible organic solvent, followed by the preparation of its lactone derivative or its secondary amine salt as an intermediate.

5. The process of claim 2, wherein said step of separating the compound of formula (I) from the culture broth is performed by purification of the alkaline aqueous extract obtained from the organic solvent extract of the fermentation broth with chromatography on a non-ionic adsorbing resin.

6. The process of claim 1, wherein the strain of *Mortierella maculata* is the *Mortierella maculata* n. sp. E-97 strain deposited at the National Collection of Agricultural and Industrial Microorganisms, Budapest, Hungary under accession number NCAIM(P)F 001266.

7. The process of claim 1, wherein the strain of *Mortierella maculata* is the *Mortierella maculata* n. sp. E-97/15/13 strain deposited at the National Collection of Agricultural and Industrial Microorganisms, Budapest, Hungary under accession number NCAIM(P)F 001267.

8. The process of claim 1, wherein the hydroxylase enzyme of the strain used for the

transformation is induced by 8-de(2-methyl-butyryl) compactin or compactin.

9. The process of claim 2, wherein a compound of formula (II) as a substrate is added into the culture parallel with the feeding step, and wherein the feeding step depends on the pH of the culture and its quantity is 0.5-1.0% related to the volume of the broth.

10. The process of claim 1, wherein the fermentation step is carried out on a medium containing a carbon source selected from the group consisting of glucose, fructose and glycerine.

11. The process of claim 1, wherein the fermentation step is carried out on a medium containing a nitrogen source selected from the group of consisting of soybean meal, peptone, casein, yeast extract and meat extract.

12. The process of claim 2, wherein the compound of formula (I) formed during the bioconversion is separated from the culture broth by adsorption from the filtrate of the broth and from the washing water of the mycelium on an anion exchange resin, eluting the compound of formula (I) from the resin, transforming the compound of formula (I) completely to its lactone form, isolating the lactone derivative, hydrolyzing the lactone derivative by sodium hydroxide, and desalting the compound of formula (I) on a non-ionic adsorption resin.

13. The process of claim 12, wherein said anion exchange resin has quaternary ammonium active groups carrying polystyrene-divinylbenzene skeleton, is used for the separation of the compound of formula (I) from the filtrate of the broth.

14. The process of claim 4, wherein the compound of formula (I) formed during the bioconversion is extracted in acid form from the broth, the broth having been acidified to the pH of 3.5-3.7, or from filtrate of the broth by a water-immiscible organic solvent.

15. The process of claim 14 wherein said water-immiscible organic solvent is ethyl acetate.

16. The process of claim 14 wherein said water immiscible organic solvent is isobutyl acetate.

17. The process of claim 5, wherein said compound of formula (I) is extracted in sodium salt form from the organic solvent by aqueous sodium hydroxide solution, and purified on a non-ionic adsorption resin.

18. The process of claim 14, wherein said compound of formula (I) is precipitated from the extract in crystalline form with a secondary amine containing alkyl-, cycloalkyl-, aralkyl- or aryl-substituents.

19. The process of claim 18, wherein the crystalline secondary amine salt is suspended in a mixture of a 1-4 carbon atom-containing alkyl ester of acetic acid and water; an equivalent quantity of sodium hydroxide is added in aqueous solution to the suspension such that an organic phase and an aqueous phase are formed; the organic and aqueous phases are separated; the aqueous phase is washed with isobutyl acetate, then clarified with activated carbon; and the aqueous solution is lyophilized.

20. The process of claim 19, wherein said alkyl ester is isobutyl ester.

21. The process of claim 18, wherein the crystalline secondary amine salt is suspended in a 1-4 carbon atom-containing alcohol; from the suspension a solution of the compound of formula (I) is prepared by adding an ethanolic solution of sodium hydroxide; and the compound of formula (I) is precipitated from the solution by acetone.

22. The process of claim 21, wherein said 1-4 carbon atom-containing alcohol is ethanol.

23. The process of claim 18, wherein the crystalline secondary amine salt is dissolved in a mixture of a 1-4 carbon atom-containing alkyl ester of a 1-4 carbon atom-containing alkane carboxylic acid and a 1-4 carbon atom-containing alcohol; and from the solution the compound of formula (I) is precipitated in crystalline form by adding sodium hydroxide.

24. The process of claim 23, wherein said mixture is an ethyl acetate-ethanol mixture.

25. The process of claim 19, wherein pravastatin is isolated from the fermentation broth via the dibenzylamine salt of the acid form of the compound of formula (I).

26. The process of claim 19, wherein the acid derivative of the compound of formula (I) is purified through its dicyclohexylamine salt.

27. The process of claim 19, wherein the acid derivative of the compound of formula (I) is purified through its dioctylamine salt.

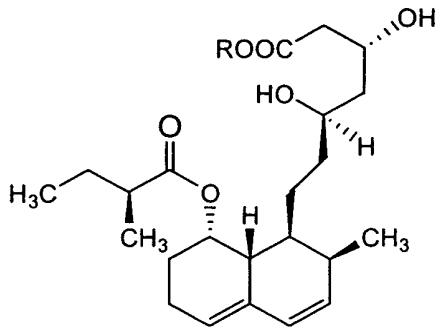
28. The process of claim 19, wherein the compound of formula (I) is purified to at least 99.5%, as measured by HPLC, using gel chromatography.

29. The process of claim 1, wherein said strain of *Mortierella maculata* is cultivated at about 25° to about 30°C.

30. A biologically pure culture of the *Mortierella maculata* n. sp. E-97 strain deposited at the National Collection of Agricultural and Industrial Microorganisms, Budapest, Hungary under accession number NCAIM(P)F 001266.

31. A biologically pure culture of the *Mortierella maculata* n. sp. E-97/15/13 strain deposited at the National Collection of Agricultural and Industrial Microorganisms, Budapest, Hungary under accession number NCAIM(P)F 001267.

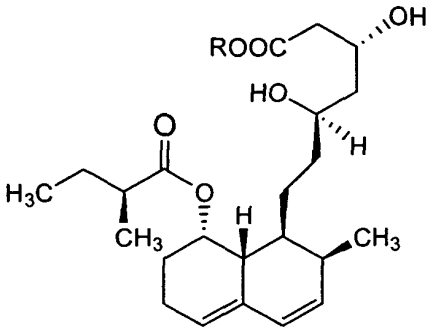
32. A *Mortierella* culture able to 6β-hydroxylate a compound of formula (II)



(II)

wherein R stands for an alkali metal or ammonium ion, consisting essentially of a novel strain *Mortierella maculata* n. sp. E-97 deposited at the National Collection of Agricultural and Industrial Microorganisms, Budapest, Hungary under accession number NCAIM(P)F 001266.

33. A *Mortierella* culture able to 6β-hydroxylate a compound of formula (II)



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